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P01/7700 0.00-0221713.1

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1. Your reference — N.86748 MN

2. Patent application number *(The Patent Office will fill in this part)* — 0221713.1

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

E-SAN LIMITED
Salsbury House
London Wall
London EC2B 2HP
United Kingdom

Patents ADP number *(if you know it)* 8467268001

If the applicant is a corporate body, give the country/state of its incorporation — United Kingdom

4. Title of the invention — TELEMEDICINE SYSTEM

5. Name of your agent *(if you have one)* — J.A. KEMP & CO.

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

14 South Square
Gray's Inn
London
WC1R 5JJ

Patents ADP number *(if you know it)* 26001

	Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*
6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number			

	Number of earlier application	Date of filing *(day / month / year)*
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8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

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Continuation sheets of this form	
Description	10
Claim(s)	3
Abstract	1
Drawing(s)	6

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Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	1
Request for preliminary examination and search *(Patents Form 9/77)*	1
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature J.A. Kemp Date 18 September 2002

J.A. KEMP & CO.

12. Name and daytime telephone number of person to contact in the United Kingdom

NICHOLLS, Michael John
020 7405 3292

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DUPLICATE

TELEMEDICINE SYSTEM

This invention relates to a telemedicine system, and in particular to a system with improved operability, thus making it particularly suitable for home health monitoring.

There are a number of chronic medical conditions in which the sufferers (or patients) are required to measure regularly some physiological parameter which characterises their condition, and to record those values. Typically such patients attend regular clinics where a clinician can review the recorded values and assess the state of health of the patient. For example, it is generally accepted that part of the effective treatment of patients suffering from asthma is the regular monitoring of their condition. In particular, daily self-measurement of lung function by patients enables clinicians to assess the severity of the illness and allows the treatment (for instance the dosage of drugs such as steroids) to be tailored to the patient's needs. Commonly, measurement of lung function is by taking peak expiratory flow readings using a Wright's peak flow meter. Patients record measurements twice daily and enter them on a peak flow graph in a patient diary. However, this system of recording depends not only on the patients remembering to note down the correct figures, but also on them entering the data accurately on the graph. At the clinic there is no way that the clinician can be entirely sure that the figure and the corresponding entry on the graph are an accurate representation of the peak flow at the time. The results are also viewed retrospectively by the clinician, who looks for trends since the last visit to the asthma clinic, and so the figures provide little information with regard to the patient's condition at that particular time, and they have limited predictive value.

Type I diabetes is another chronic condition which can be treated or managed using home monitoring. Type I diabetes is treated with insulin (by injection several times a day) and by eating a healthy diet. However, Type I diabetics need to monitor their blood glucose levels regularly. This typically requires a small blood sample to be obtained by pricking the skin, usually on a finger, and placing the sample on a test

strip which is read by an electronic glucose meter. Self-monitoring in this way helps to detect when blood sugar levels may be too low, in which case sugar must be taken (for example a sweet drink or meal), or when the blood sugar levels may become too high (for instance at times of illness) when the patient may become dehydrated and possibly comatose. Patients typically attend a diabetes clinic every three months or so for blood tests, recordal of height and weight and blood pressure and other checks, such as eye checks for retinopathy. However, with some patients adherence to the management program (of making regular blood glucose readings) is poor and this increases the risk of developing long-term complications. For instance, readings are often missed, in which case patients sometimes fabricate them, or they may be adjusted when recording them in a patient diary. Better adherence to the management program can decrease the occurrence of long-term diabetic complications.

To overcome some of the problems of manual recordal in a patient diary, various technologically-based recordal systems have been proposed. Typically such proposals have involved the use of an electronic physiological data acquisition unit (such as an electronic glucose meter or electronic peak flow meter as above) whose measurements are downloaded onto a data storage device. The stored data may be reviewed at the regular clinics, or in some telemedicine proposals the data may be transferred to a personal computer and sent to a clinic or clinician via the internet. However, the process of downloading the data and transmitting it to the clinician via the internet requires a familiarity with computer systems which not all patients have or desire to attain. Further, it is time-consuming and often troublesome to obtain a connection via the internet. The system is also problematic if the patient is not at home. So the use of this technology has tended to degrade compliance with self-monitoring techniques rather than improve it. Further, none of these systems have proved useful in practice, because a clinician typically looks after hundreds of patients.

It is an object of the present invention to provide an improved telemedicine system, in particular in which the operability is improved so that it enhances the

adherence to self-monitoring by patients.

The present invention provides a telemedicine system in which the physiological data is acquired and transmitted to a remote server automatically upon the readings being taken, without the intervention of the patient. In more detail, the present invention provides a telemedicine system comprising a patient-based physiological data acquisition and transmittal device connectable via a wireless network to transmit physiological data to a remote server, wherein the patient-based measurement and data transmittal device comprises:

an electronic physiological data acquisition unit for measuring a physiological parameter of a patient to acquire and output data representing the parameter;

a wireless transmitter which upon receiving the output data from the data acquisition unit automatically transmits the output data via the wireless network to the remote server.

Thus preferably the wireless transmitter is adapted to receive automatically the output data from the physiological data acquisition unit on data acquisition thereby, and thereupon automatically to transmit the output data immediately in real time to the remote server. Preferably the wireless transmitter is adapted to establish a connection to the wireless network automatically when it is switched on and to maintain the connection while switched on. Thus the patient is not required to download the data, this is automatic and immediate upon data acquisition. Further, the transmittal of the data is also automatic, again, without bothering the patient. All the patient has to do is switch the device on, take the reading (at which point the readings are automatically sent to the remote server) and switch the device off.

The wireless network may be a packet-switched network, preferably public, such as the GPRS, 3G, PDC-P or EDGE network.

The wireless transmitter may be a cellular telephone or personal digital assistant (PDA) with cellular telephony capability, currently known as a smart phone. A software application may be provided on the cellular telephone/PDA to interface with the physiological data acquisition unit and to control data transmission to the

remote server. Thus the patient can switch on the cellular telephone/PDA, select an icon representing the software application, after which the cellular telephone/PDA automatically interfaces with the data acquisition unit and transmits the data via the wireless network to the remote server. The device may be adapted to check the acquired data for compliance with pre-set conditions, such as concerning the quality or completeness of the readings or the condition of the patient. The data may be displayed on the device so that the patient can see that the readings are complete and assess their condition themselves to some extent. However, the automatic transmittal of the data to the remote server means that the patient cannot self-edit the data.

In the event of a network connection being unavailable, the device stores the data and may automatically re-transmit it later when a connection becomes available.

Preferably the remote server immediately processes the data on reception to check the condition of the patient. It may respond with an acknowledgement of the data, and also perhaps with a message related to the patient's condition (for instance to change the treatment regime or to attend a clinic or to seek emergency medical assistance). The remote server also preferably formats the data for delivery and display to a clinician. Thus a clinician may access the data, for instance by viewing it as a web page via the internet or some other network, and the clinician may also send messages to the patient via the network. The remote server may comprise a data analyser for identifying trends in the data, and a message generator for generating automatically messages to be output to at least one of the patient and clinician.

The fact that the server can automatically analyse the data and alert the relevant clinician means that a closed loop including the clinician is produced in the patient management process.

The wireless transmitter may be in the form of a cellular telephone/PDA separate from the physiological data acquisition unit such as an electronic flow meter, electronic blood glucose meter, blood pressure monitor or heart rate monitor, the two units being connectable, for instance by a cable. Alternatively, the wireless transmitter function may be integrated into the physiological data acquisition unit.

The invention will be further described by way of example with reference to the accompanying drawings in which:-

Figure 1 is a schematic illustration of a first embodiment of the invention;

Figure 2 is a flow diagram showing the operation of the device in one embodiment of the invention;

Figure 3 illustrates a screen display from the first embodiment of the invention;

Figure 4 is a plot of data obtained using an embodiment of Figure 1;

Figure 5 is a schematic illustration of a second embodiment of the invention;

Figure 6 is a flow diagram of the operation of part of an embodiment of the invention;

Figure 7 is a flow diagram of another part of the operation of an embodiment of the invention; and

Figure 8 illustrates the data packet format.

A first embodiment of the invention as illustrated in Figure 1 is for use by patients suffering from asthma. The system includes an electronic flow meter 1 which is connected via a cable 3 to a GPRS cellular telephone 5. The cellular telephone 5 is connectable via the GPRS wireless network 7 to a remote server 9. As illustrated in Figure 1 a clinician such as a general practitioner (GP) 11 may communicate with the server via the internet 13 using a conventional telephone line 15 and ISP 17.

GPRS telephones can maintain a permanent connection to the GPRS network whenever they are on. Thus the user does not need to initiate any form of dial-up or connection or session request. In this embodiment the GPRS telephone is provided with a software application which handles the interfacing to the electronic flow meter 1 and the transmission of the data to the remote server 9. The steps required by the patient, together with the automatic operations which are conducted in the background (invisible to the patient) are illustrated in Figure 2. The first steps 201, 203 are for the patient to connect the GPRS telephone and peak flow meter together using the cable 3 and to switch on the phone and peak flow meter (these steps may be

in the other order). As just mentioned, when the GPRS telephone is switched on it automatically establishes a connection to the GPRS network without the intervention of the user as illustrated at 205. The user selects in step 207 an icon on the GPRS telephone to start the software application for taking the measurement. In this embodiment the GPRS telephone is a conventional one which has other functions. Of course, if the GPRS functionality is dedicated to the flow rate meter (so that other functionality is not required) the step of selecting the software application may be eliminated by starting the application automatically on switching on. The operation of the GPRS telephone 5 under control of this software application is illustrated in Figures 6 and 7. As illustrated in steps 601 and 602 the telephone starts a child process to read the physiological data from the flow meter 1. In this embodiment the data is made available at an RS-232 port on the peak flow meter 1. Therefore in step 602 the telephone opens the RS-232 port and initialises ready to receive data, for instance by setting time-outs, baud rate etc. At step 209 the telephone then requests that the patient takes the peak flow reading (in fact three times) by displaying the instruction as shown in Figure 3. It then waits for data as illustrated in step 603 and checks the received data for completeness as illustrated in step 604. Once the data is complete the software formats the data for transmission over the GPRS network by forming it into appropriate data packets which include a patient identifier, a time stamp and the raw data from the peak flow meter. These data packets are automatically transmitted in real time (i.e. immediately upon receipt of data from the peak flow meter) as illustrated in step 605. GRPS once connected allows data to be sent as though on a normal network (e.g. LAN or Etternet). A TCP/IP socket connection is opened by the software to the server and the data is transmitted in the structure provided, as illustrated in Figure 8. The server expects the data in that structure, so understands the received packet.

As illustrated in Figure 2, the sending of the data to the server as step 210 is invisible to the user and occurs as the user is blowing into the peak flow meter, thus each reading is sent as it is taken. The remote server 9 acknowledges the data it has received at step 212 and on receipt of the acknowledgement the GPRS telephone 5

indicates to the patient that the measurement is satisfactory and that the procedure can be concluded at step 216. In the event of the network connection being unavailable the GPRS telephone stores the data for later transmission as indicated in step 218.

Figure 7 illustrates in more detail the data transmission process. In step 701 the data is saved to a file marked as unsent. When a connection becomes available in step 703 the connection to the server is opened and the readings (and any previously unsent readings) are sent to the server in step 705. The software waits for an acknowledgement from the server at step 707, and if it receives the acknowledgement the data is marked as sent and the procedure terminated at step 709. However, if no acknowledgement is received within a time-out period then the data is left as unsent and a further attempt is made later as illustrated at 711.

At the server 9 the data is analysed and may be compared with previous known trends for the patient. If the new measurements are within the limits appropriate for the patient, the data is simply added to the patient's file on the server. However, if the readings are identified as causing concern, the server will notify the clinician 11 who can then access the relevant patient data on the server via a secure web page, and can also contact the patient (either by using the GPRS network 7 or in another way). The readings stored on the server will of course be accessed by the clinician during a patient's regular visit to the asthma clinic. In contrast to manually recorded data, the clinician can be sure that the data is reliable and quantitative.

If no measurements have been received at the server for more than a pre-set length of time, such as a day, the server automatically sends a message (e.g. a text message) to the GPRS phone requesting new data from the patient.

As illustrated in Figure 3 the data collected may also be displayed to the patient. The cellular telephone may also include the provision for the patient to enter comments, for instance to keep an electronic patient diary. This may also be transmitted to the remote server 9 along with the peak flow readings.

Although only one patient device 1, 3, 5 is illustrated in Figure 1, it will of course be appreciated that many patients will be provided with the devices, all of

whom may be served by the same remote server 9.

Figure 4 illustrates seventy days worth of peak flow readings for an example patient using the embodiment of Figure 1. The daily peak flow values are shown by the dotted line, while the trend (explained later) is shown by the solid line.

It will be appreciated that the system above is an improvement over requiring manual recording of peak flow readings, and also over previous proposals for telemedicine systems. The operations required by the patient are very simple and quick and do not require any significant familiarity with computer systems, modems or the internet. All that is required is that the equipment is switched on, connected together and the readings taken. The downloading, formatting and transmission of data are entirely invisible to the user.

Although the embodiment above has been described with reference to asthma suffers who need to take peak expiratory flow readings, the system is also applicable to other types of chronic conditions using appropriate electronic medical devices.

For example, Figure 5 illustrates a system for monitoring of blood sugar levels for Type I diabetics. This is based on the use of an electronic blood glucose meter 51 of the type which measures blood glucose level in a sample of blood applied by the patient to a test strip 52 inserted into the meter. As before, the blood glucose meter 51 is connected by a RS-232 cable 53 to a GPRS telephone 55 which communicates with a remote server 9 and with a clinician 61 in the same way as the first embodiment of the invention. Thus the patient is required to switch the blood glucose meter on, connect the RS-232 cable 53 to the GPRS telephone 55 and then place a drop of blood on the reagent strip 52 and introduce it into the blood glucose meter. The introduction of the test strip triggers the measurement and the delivery of data to the GPRS telephone 55 which automatically checks, displays, formats and transmits the data to the remote server 9 as before. Again, the remote server can analyse the data and automatically notify any significant departure from expected behaviour to the clinician 61 and possibly to the patient as well. Further, when the patient attends a diabetes clinic, the clinician can access the patient data from the server 9, again in the sure knowledge that the data is reliable and quantitative.

As mentioned above these embodiments of the invention include the facility for automatic data analysis at the server 9, for instance to spot trends in the data for individual patients which might require medical intervention. As an example, the server may smooth the data using a scalar Kalman filter, the aim being to spot impending events as they develop (e.g. a significant decrease in peak flow readings in the run-up to a possible "asthma attack") and to alert the clinician and/or the patient. This form of event detection is tuned to each patient's characteristics and the advice sent to the patient, preferably mediated by the clinician, is to vary the medication and/or its dosage. In Figure 4, the trend calculated by means of a Kalman smoother is illustrated in the solid line. The Kalman filter is a generic framework for analysis of a linear dynamical system (in this case, the time-dependent peak flow, blood glucose or blood pressure readings). Using a process model, the next state x is computed from the current state using a transition matrix *A* and assuming first-order (Markov) dynamics with process noise Q i.e. X(t+1)=AX(t)+Q. The observation model relates the measurements Y to the state of the system via the observation matrix *C* and observation noise R, ie. Y(t)=CX(t)+R. The process and observation noise Q and R are assumed to be independent and to have zero mean. The peak flow values (or blood glucose levels or blood pressure measurements) can be modelled with a scalar Kalman filter which assumes that the next value will be the same as the current value (this means that A is equal to 1) plus some process noise characterising normal variability. In addition, it is also assumed that *C*=1, i.e. the peak flow value (or blood glucose level or blood pressure measurement) is both the measurement Y and the state X of the system. In this instance the scalar Kalman filter is run as a Kalman smoother of the raw data, which, with suitable values for the process and measurement noise, allows the filter to perform on-line trend analysis of a noisy or oscillatory set of readings as shown in the above plot. In the plot in Figure 4 the process noise Q was taken as 10 and the observation noise R as 100 with initial values of the state X as 300 and of the state variance V as 40. Thus, the trend in Figure 4, shown as a continuous line, is not affected by the highly oscillatory nature of the readings (shown as a dotted line) between days 40 and 50, and correctly

identifies the clinically significant dip in peak flow values starting at day 60, which was caused by a rise in pollen count and associated hay fever.

The use of the above system is not only beneficial to the patient in reducing the time and trouble needed for self-monitoring, but also manifestly improves the reliability of the data itself. Also, with conventional systems self-monitoring by patients just occurs independently, in the field, and is only reviewed at regular clinics. With this system the clinician is always available in the patient management process loop. This means that the patient's condition can be monitored and controlled more effectively - in near real time, which in turn reduces the likelihood of long-term complications and reduces the need for emergency or extreme measures caused when the patient's condition has departed too far from an acceptable stable state. Such changes in condition can be identified sooner, particularly with the automatic trend analysis at the server, rather than only when the patient's condition becomes critical or only when the patient visits the clinic. It therefore reduces the need for serious medical intervention which is of benefit both to the patient and to the medical services.

With the systems described above, the fact that the monitoring can be virtually guaranteed to be accurate (because of the automatic transmission of the raw data), regular (because of the ease of the procedure and the availability of reminders from the server), and can spot dangerous trends means that the frequency of clinic visits could be reduced. This is therefore more convenient for the patient and cost-effective for the medical services.

CLAIMS

1. A telemedicine system comprising a patient-based physiological data acquisition and transmittal device connectable via a wireless network to transmit physiological data to a remote server, wherein the patient-based measurement and data transmittal device comprises:

an electronic physiological data acquisition unit for measuring a physiological parameter of a patient to acquire and output data representing the parameter;

a wireless transmitter which upon receiving the output data from the data acquisition unit automatically transmits the output data via the wireless network to the remote server.

2. A telemedicine system according to claim 1 wherein the wireless transmitter is adapted to receive automatically the output data from the physiological data acquisition unit on data acquisition thereby, and thereupon automatically to transmit the output data immediately in real time to the remote server.

3. A telemedicine system according to claim 1 or 2 wherein the wireless transmitter is adapted to establish a connection to the wireless network automatically when it is switched on and to maintain the connection while switched on.

4. A telemedicine system according to claim 1, 2 or 3 wherein the wireless network is a packet-switched network.

5. A telemedicine system according to claim 4 wherein the wireless network is a public network.

6. A telemedicine system according to claim 5 wherein the wireless network is the General Packet Radio Service (GPRS) network.

7. A telemedicine system according to claim 1, 2 or 3 wherein the wireless network is the 3G, PDC-P or EDGE network.

8. A telemedicine system according to any one of the preceding claims wherein the wireless transmitter is a cellular telephone/pda.

9. A telemedicine system according to claim 8 wherein a software application is provided on the cellular telephone/pda to interface with the physiological data acquisition unit and to control data transmission to the remote server.

10. A telemedicine system according to any one of the preceding claims wherein the patient-based measurement and data transmittal device is adapted to check the acquired data for compliance with preset conditions.

11. A telemedicine system according to claim 10 wherein the preset conditions relate to the quality or completeness of the data or the condition of the patient.

12. A telemedicine system according to any one of the preceding claims wherein the patient-based measurement and data transmittal device comprises a display for displaying the data to the patient.

13. A telemedicine system according to any one of the preceding claims wherein the patient-based measurement and data transmittal device stores the data if a network connection is unavailable and automatically retransmits it later when a network connection is available.

14. A telemedicine system according to any one of the preceding claims wherein the remote server processes the data to check the condition of the patient and responds with a message via the wireless network.

15. A telemedicine system according to any one of the preceding claims wherein the remote server formats the data for delivery and display to a clinician.

16. A telemedicine system according to any one of the preceding claims wherein the remote server comprises a data analyser for identifying trends in the data and a message generator for generating messages to be output to at least one of the patient and a clinician.

17. A telemedicine system according to claim 16 wherein the data analyser comprises a Kalman smoother for smoothing the data.

18. A telemedicine system according to any one of the preceding claims wherein the physiological data acquisition unit is one of: an electronic flow meter for recording Peak Expiratory Flowrate, an electronic blood glucose meter, a blood pressure monitor, and a heart rate monitor.

19. A telemedicine system according to any one of the preceding claims wherein the physiological data acquisition unit and wireless transmitter are integrated as a single device.

ABSTRACT

TELEMEDICINE SYSTEM

A telemedicine system for monitoring chronic conditions such as asthma or diabetes includes an electronic measurement device such as an electronic peak expiratory flow meter or an electronic blood glucose meter, connected to a GPRS cellular telephone. The cellular telephone automatically receives, formats and transmits the data on acquisition by the medical device to a remote server. The server may acknowledge the data and make the data available to a clinician. The server may also analyse the data and provide automatic alerts to the patient and/or clinician in the event of the data causing concern. The formatting and transmission of the data from the telephone to the server occurs in real time as the measurements are taken and is invisible to the patient.

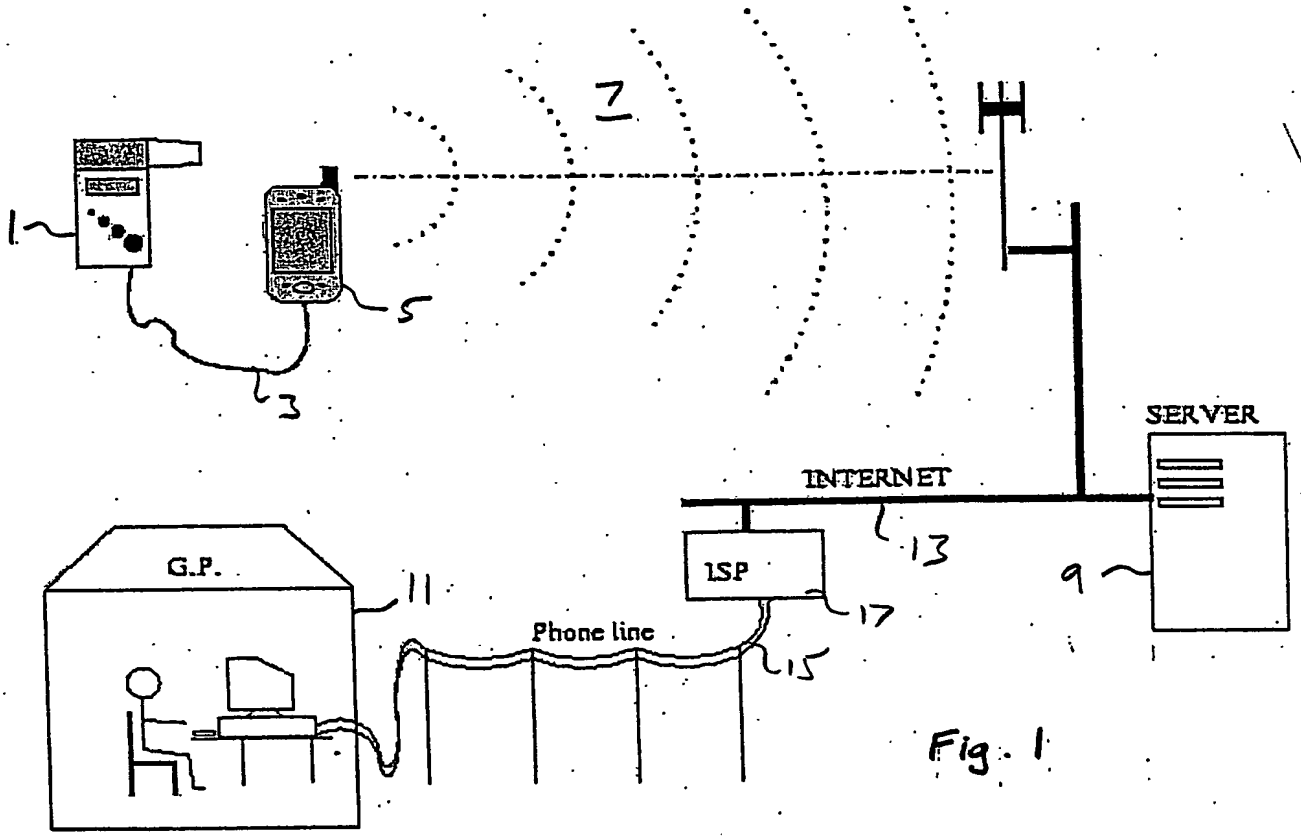

1
3
5
7
SERVER
INTERNET
13
ISP
17
9
G.P.
11
Phone line
15

Fig. 1

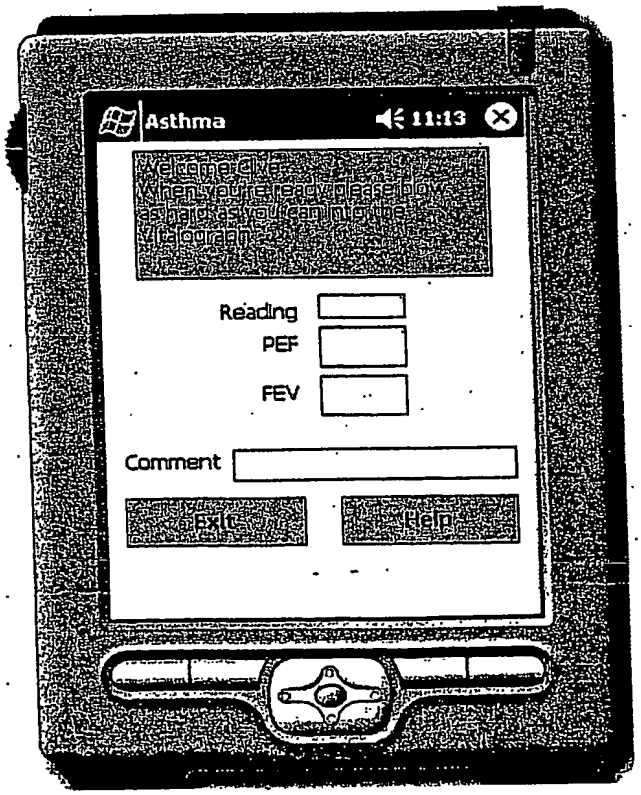

Asthma
11:13
Reading
PEF
FEV
Comment
Exit
Help

Fig. 3

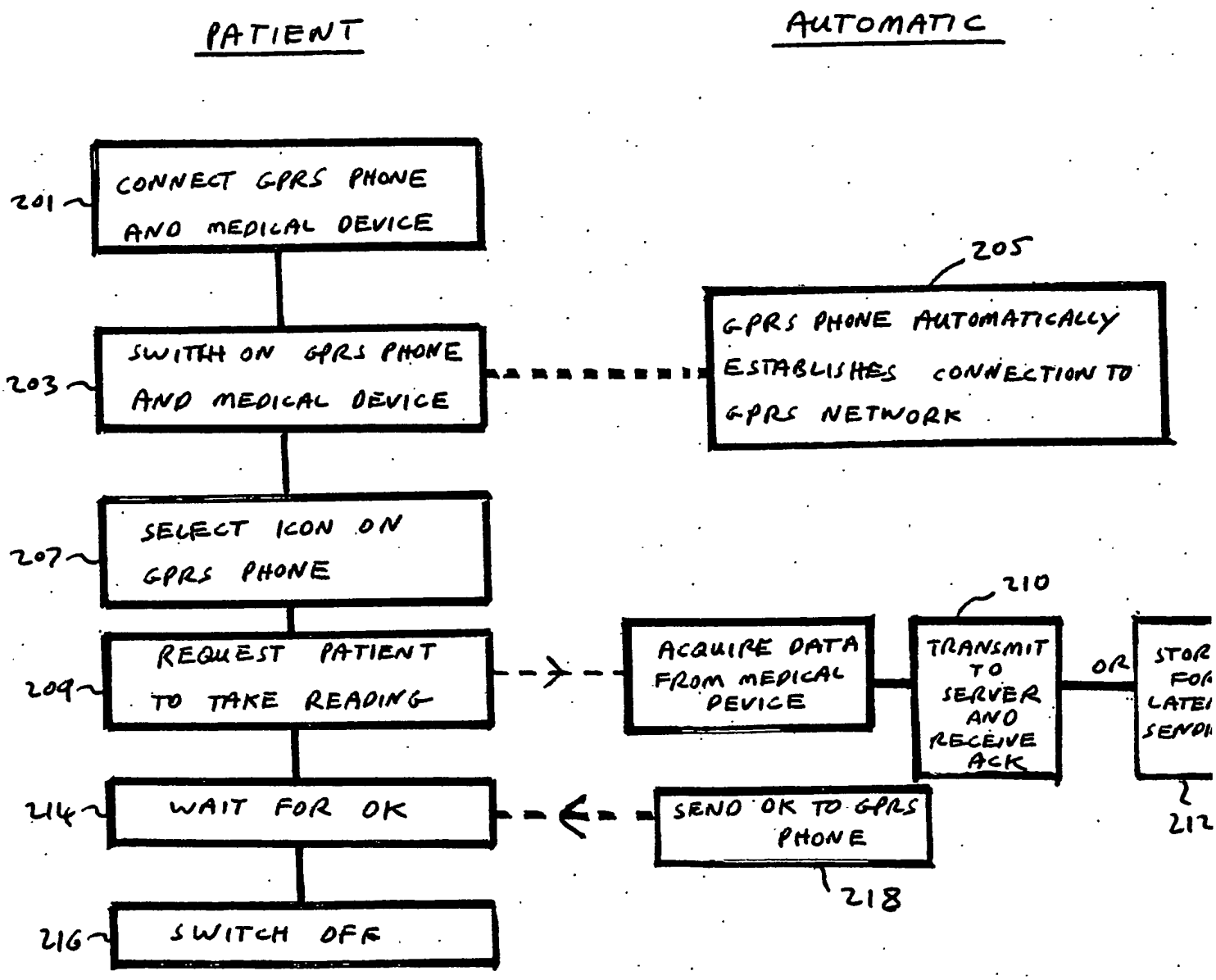

PATIENT
AUTOMATIC
201
CONNECT GPRS PHONE AND MEDICAL DEVICE
203
SWITCH ON GPRS PHONE AND MEDICAL DEVICE
205
GPRS PHONE AUTOMATICALLY ESTABLISHES CONNECTION TO GPRS NETWORK
207
SELECT ICON ON GPRS PHONE
209
REQUEST PATIENT TO TAKE READING
ACQUIRE DATA FROM MEDICAL DEVICE
210
TRANSMIT TO SERVER AND RECEIVE ACK
OR
STOR FOR LATE SENDI
212
214
WAIT FOR OK
SEND OK TO GPRS PHONE
218
216
SWITCH OFF

Fig. 2

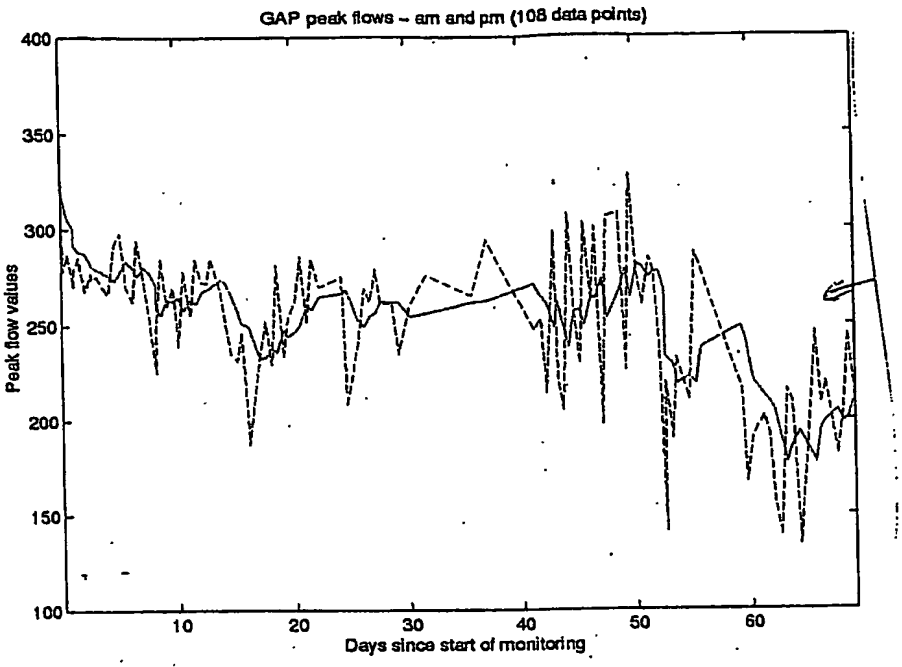

GAP peak flows – am and pm (108 data points)
Peak flow values
Days since start of monitoring
400
350
300
250
200
150
100
10
20
30
40
50
60

Fig. 4

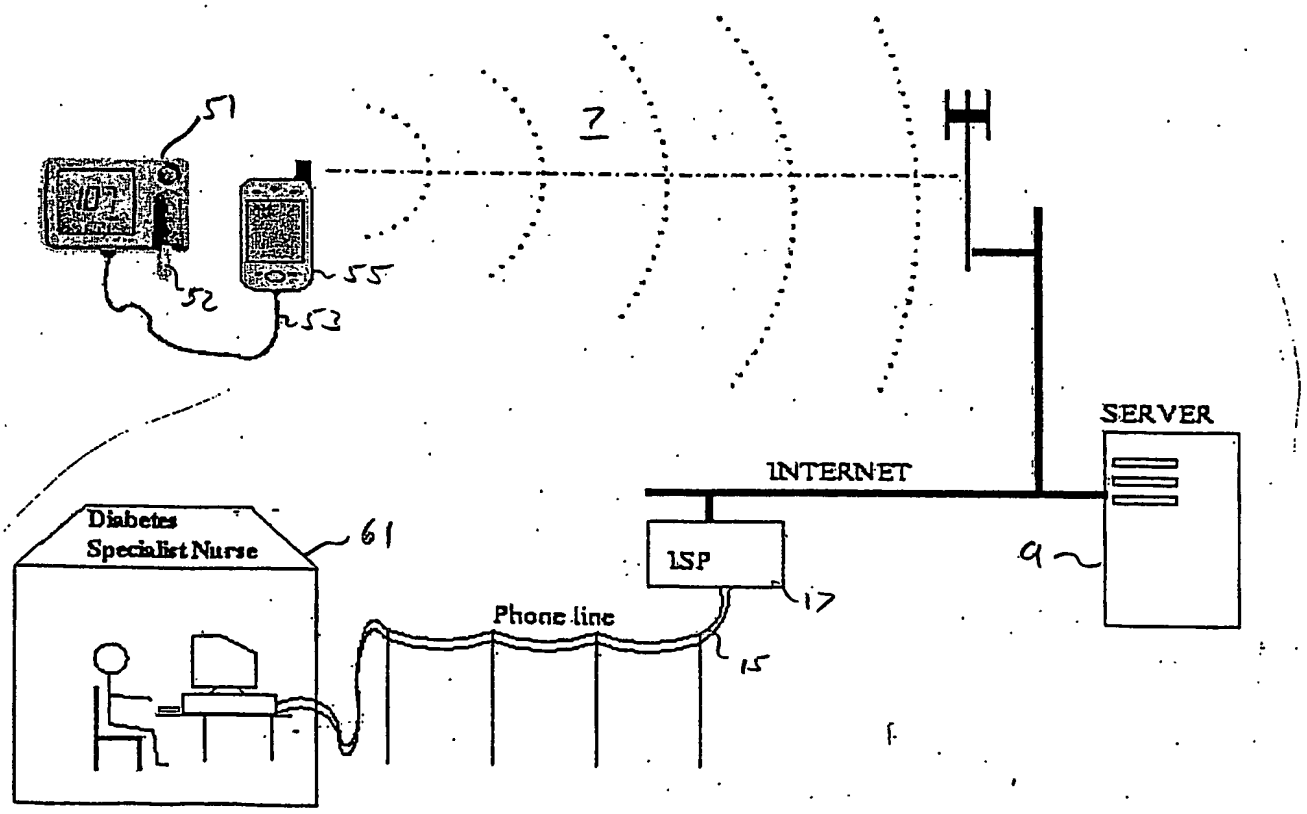

51
7
55
52
53
SERVER
INTERNET
Diabetes
Specialist Nurse
61
ISP
17
9
Phone line
15

Fig. 5

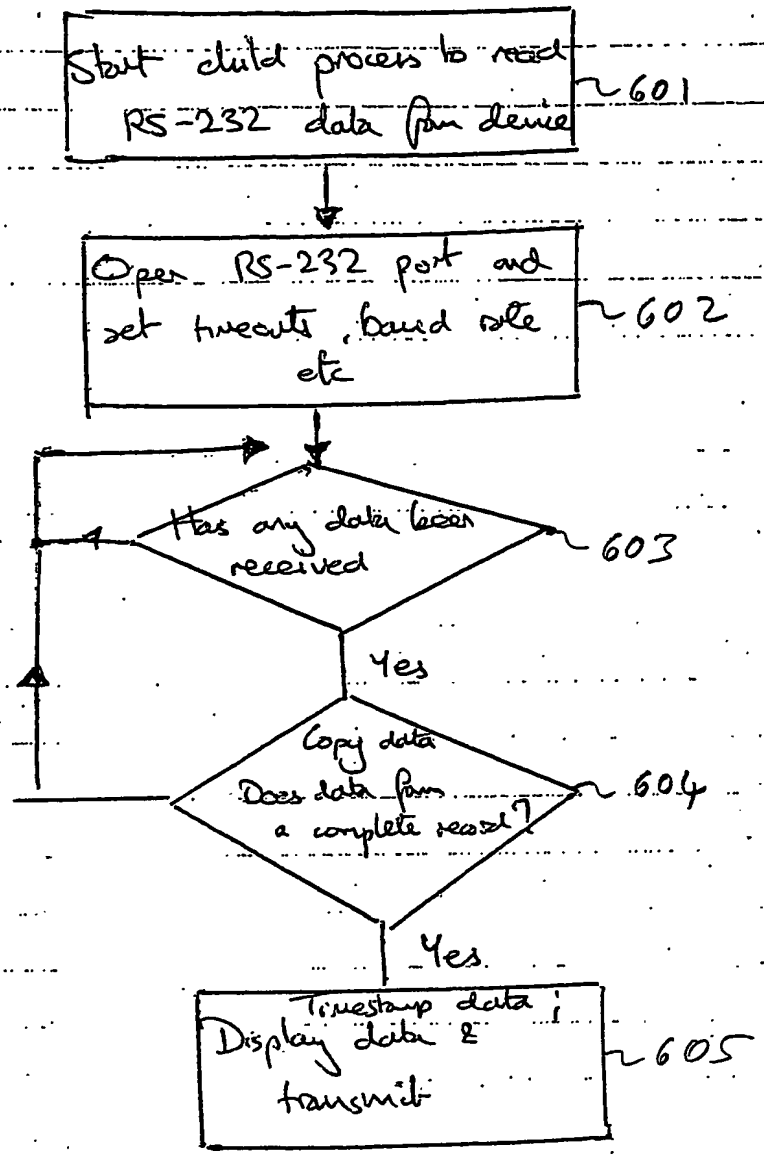

Start child process to read RS-232 data from device
601
Open RS-232 port and set timeouts, baud rate etc
602
Has any data been received
603
Yes
Copy data
Does data form a complete record?
604
Yes
Timestamp data
Display data & transmit
605

Fig. 6

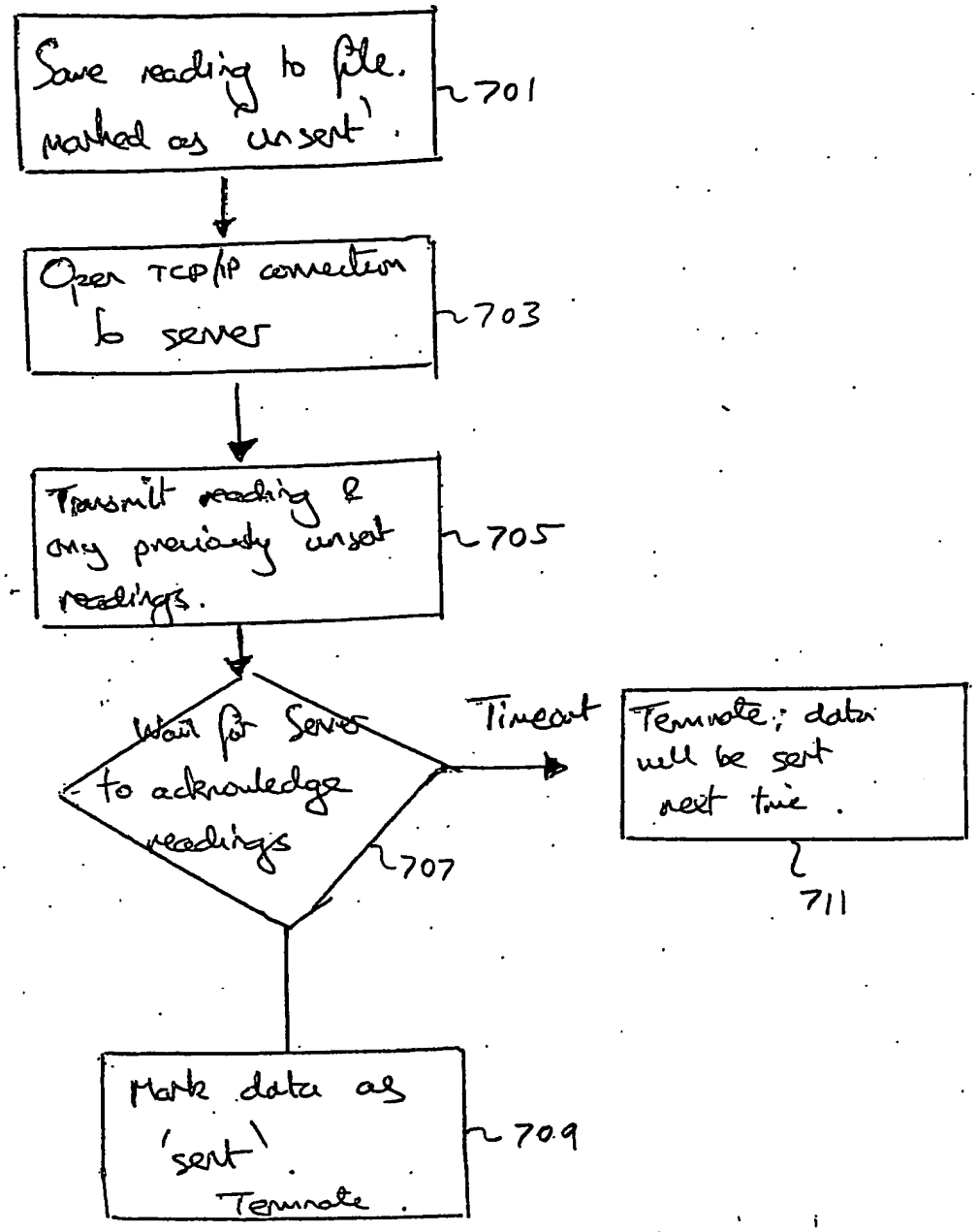

Save reading to file. marked as 'unsent'.
701
Open TCP/IP connection to server
703
Transmit reading & any previously unsent readings.
705
Wait for Server to acknowledge readings
707
Timeout
Terminate; data will be sent next time.
711
Mark data as 'sent'. Terminate.
709

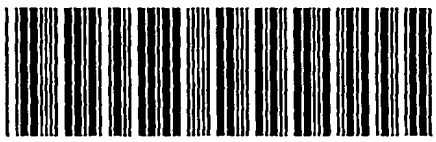
Fig. 7

Data Packet Format

```
# define MSG_LENGTH 32
    struct aethra_reading {
            long secs;
            char data [MSG_LENGTH];
            char comment [64];
            };
    struct aethra_packet {
            long packet_id;
            struct aethra_reading reading [64];
            int n_readings;
            int endianinit;          /* Always set to 1 */
            };
```

Fig. 8

PCT Application
GB0304029



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